

## REMARKS

Claims 57, 59-80 and 82-102 are presently pending in the case. Claims 57 and 80 have been amended. The claim amendments are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC §112**

The Examiner rejected claims 57, 59-80 and 82-102 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Though Applicant disagrees with the rejection and reserves the right to pursue the claims in a continuing application, the rejection is believed to be moot in view of the above amendments.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 57, 59-77, 80 and 82-100 under 35 USC §103(a) as being unpatentable over U.S. Patent 5,855,913 to Hanes et al (hereinafter Hanes et al) in view of U.S. Patent 6,120,751 to Unger (hereinafter Unger) as evidenced by U.S. Patent 5,776,488. The rejection is traversed.

Hanes et al and Unger do not render independent claim 57, for example, unpatentable. Claim 57 is to an inhaleable powder composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, inter alia a structural matrix comprising phospholipid and calcium. Hanes et al does not teach an inhaleable powder comprising particulate microstructures comprising phospholipid and calcium (as acknowledged by the Examiner). Unger does not teach the addition of calcium in a manner where one of ordinary skill in the art would have found it obvious to

arrive at the invention of claim 57, as discussed in the Applicant's previous response.

In addition, Hanes et al and Unger do not render claim 57 as amended, unpatentable. Claim 57 recites: "wherein the particulate microstructures comprise greater than about 50% phospholipid." Hanes et al does not teach particulate microstructures that comprise greater than about 50% phospholipid. Instead, Hanes et al particles are primarily composed of polymer (see columns 5 and 6). Unger, which is relied upon to teach the addition of calcium, does not make up for the deficiency in Hanes. Furthermore, the motivation provided by the Examiner (see Office Action page 7) for incorporating the calcium of Unger with the Hanes et al particles was based on the calcium's interaction with the polymer. This motivation would not exist if the particles were primarily phospholipid, as set forth in claim 57. Thus, there is no prima facie case of obviousness established against claim 57, as amended.

For at least these reasons, claim 57 is not properly rejectable under 35 USC §103(a) as being unpatentable over Hanes et al and Unger. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Unger could be applied, with a reasonable likelihood of success, to Hanes et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined the teachings in a manner that would result in the invention of claim 57 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that invention set forth in claim 57 is particularly useful for delivering an active agent to the lungs in a reproducible manner. Thus, claim 57 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 57 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 59-79 which depend from claim 57 and are not rendered unpatentable by Hanes et al and Unger for at least the same reasons as claim 57.

Hanes et al and Unger also do not render independent claim 80, for example, unpatentable. Claim 80 is to a composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, inter alia a structural matrix comprising phospholipid and calcium. Hanes et al does not teach an inhaleable powder comprising particulate microstructures comprising phospholipid and calcium (as acknowledged by the Examiner). Unger does not teach the addition of calcium in a manner where one of ordinary skill in the art would have found it obvious to arrive at the invention of claim 80, as discussed in the Applicant's previous response.

In addition, Hanes et al and Unger do not render claim 80 as amended, unpatentable. Claim 80 recites: "wherein the particulate microstructures comprise greater than about 50% phospholipid." Hanes et al does not teach particulate microstructures that comprise greater than about 50% phospholipid. Instead, Hanes et al particles are primarily composed of polymer (see columns 5 and 6). Unger, which is relied upon to teach the addition of calcium, does not make up for the deficiency in Hanes. Furthermore, the motivation provided by the Examiner (see Office Action page 7) for incorporating the calcium of Unger with the Hanes et al particles was based on the calcium's interaction with the polymer. This motivation would not exist if the particles were primarily phospholipid, as set forth in claim 80. Thus, there is no prima facie case of obviousness established against claim 80, as amended.

For at least these reasons, claim 80 is not properly rejectable under 35 USC §103(a) as being unpatentable over Hanes et al and Unger. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Unger could be applied, with a reasonable likelihood of success, to Hanes et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined the teachings in a manner that would result in the invention of claim 80 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has

unexpectedly found that invention set forth in claim 80 is particularly useful for delivering an active agent to the lungs in a reproducible manner. Thus, claim 80 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 80 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 82-102 which depend from claim 80 and are not rendered unpatentable by Hanes et al and Unger for at least the same reasons as claim 80.

The Examiner rejected claims 78 and 101 under 35 USC §103(a) as being unpatentable over Hanes et al in view of Unger, and further in view of U.S. Patent 4,201,774 to Igarashi et al (hereinafter Igarashi et al). The rejection is traversed.

Claims 78 and 101 depend from claims 57 and 80, respectively. Hanes et al and Unger do not render claims 57 and 80 unpatentable, as discussed above. Igarashi et al which is relied on by the Examiner to teach the use of antibiotics as an active agent does not make up for the deficiencies of Hanes et al and Unger with regard to claims 57 and 80. Thus, claims 78 and 101 are allowable for at least the reason that they depend from allowable claims.

The Examiner rejected claims 79 and 102 under 35 USC §103(a) as being unpatentable over Hanes et al in view of Unger, and further in view of U.S. Patent 5,776,488 to Benson et al (hereinafter Benson et al). The rejection is traversed.

Claims 79 and 102 depend from claims 57 and 80, respectively. Hanes et al and Unger do not render claims 57 and 80 unpatentable, as discussed above. Benson et al which is relied on by the Examiner to teach the use of fungicides as an active agent does not make up for the deficiencies of Hanes et al and Unger with regard to claims 57 and 80. Thus, claims 79 and 102 are allowable for at least the reason that they depend from allowable claims.

The Examiner rejected claims 57, 59-77, 80 and 82-100 under 35 USC §103(a) as being unpatentable over Hanes et al in view of U.S. Patent 6,248,720 to Mathiowitz et al (hereinafter Mathiowitz et al) or U.S. Patent 5,149,543 to Cohen et al (hereinafter Cohen et al). The rejection is traversed.

Hanes et al and Mathiowitz et al or Cohen et al do not render independent claim 57, for example, unpatentable. Claim 57 is to an inhaleable powder composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, inter alia a structural matrix comprising phospholipid and calcium. Hanes et al does not teach an inhaleable powder comprising particulate microstructures comprising phospholipid and calcium (as acknowledged by the Examiner). Mathiowitz et al and Cohen et al do not teach the addition of calcium in a manner where one of ordinary skill in the art would have found it obvious to arrive at the invention of claim 57, as discussed in the Applicant's previous response.

In addition, Hanes et al and Mathiowitz et al or Cohen et al do not render claim 57 as amended, unpatentable. Claim 57 recites: "wherein the particulate microstructures comprise greater than about 50% phospholipid." Hanes et al does not teach particulate microstructures that comprise greater than about 50% phospholipid. Instead, Hanes et al particles are primarily composed of polymer (see columns 5 and 6). Mathiowitz et al and Cohen et al both teach polymeric particles and do not make up for the deficiency in Hanes. Furthermore, there is no motivation for incorporating the calcium of Mathiowitz et al or Cohen et al with the Hanes et al particles. Thus, there is no prima facie case of obviousness established against claim 57, as amended.

For at least these reasons, claim 57 is not properly rejectable under 35 USC §103(a) as being unpatentable over Hanes et al and Mathiowitz et al or Cohen et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Mathiowitz et al or Cohen et al could be applied, with a reasonable likelihood of success, to Hanes et al.

There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 57 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that invention set forth in claim 57 is particularly useful for delivering an active agent to the lungs in a reproducible manner. Thus, claim 57 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 57 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 59-79 which depend from claim 57 and are not rendered unpatentable by Hanes et al and Mathiowitz et al or Cohen et al for at least the same reasons as claim 57.

Hanes et al and Mathiowitz et al or Cohen et al also do not render independent claim 80, for example, unpatentable. Claim 80 is to a composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, inter alia a structural matrix comprising phospholipid and calcium. Hanes et al does not teach an inhaleable powder comprising particulate microstructures comprising phospholipid and calcium (as acknowledged by the Examiner). Mathiowitz et al and Cohen et al do not teach the addition of calcium in a manner where one of ordinary skill in the art would have found it obvious to arrive at the invention of claim 80, as discussed in the Applicant's previous response.

In addition, Hanes et al and Mathiowitz et al or Cohen et al do not render claim 80 as amended, unpatentable. Claim 80 recites: "wherein the particulate microstructures comprise greater than about 50% phospholipid." Hanes et al does not teach particulate microstructures that comprise greater than about 50% phospholipid. Instead, Hanes et al particles are primarily composed of polymer (see columns 5 and 6). Mathiowitz et al and Cohen et al both teach polymeric particles and do not make up for the deficiency in Hanes. Furthermore, there is no motivation for incorporating the calcium of Mathiowitz et al or Cohen et al with the Hanes et al particles. Thus, there is no prima facie case of obviousness established against claim 80, as amended.

For at least these reasons, claim 80 is not properly rejectable under 35 USC §103(a) as being unpatentable over Hanes et al and Mathiowitz et al or Cohen et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Mathiowitz et al or Cohen et al could be applied, with a reasonable likelihood of success, to Hanes et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 80 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that invention set forth in claim 80 is particularly useful for delivering an active agent to the lungs in a reproducible manner. Thus, claim 80 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 80 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 82-102 which depend from claim 80 and are not rendered unpatentable by Hanes et al and Mathiowitz et al or Cohen et al for at least the same reasons as claim 80.

The Examiner rejected claims 57, 59-77, 80 and 82-100 under 35 USC §103(a) as being unpatentable over Hanes et al in view of a 1975 Publication by Papahadjopoulos et al (hereinafter Papahadjopoulos et al). The rejection is traversed.

Hanes et al and Papahadjopoulos et al do not render independent claim 57, for example, unpatentable. Claim 57 is to an inhaleable powder composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, inter alia a structural matrix comprising phospholipid and calcium. Hanes et al does not teach an inhaleable powder comprising particulate microstructures comprising phospholipid and calcium (as acknowledged by the Examiner). Papahadjopoulos et al does not teach the addition of calcium in a manner where one of ordinary skill in the art would have found it obvious to arrive at the invention of claim 57, as discussed in the

Applicant's previous response.

In addition, Hanes et al and Papahadjopoulos et al do not render claim 57 as amended, unpatentable. Claim 57 recites: "wherein the particulate microstructures comprise greater than about 50% phospholipid." Hanes et al does not teach particulate microstructures that comprise greater than about 50% phospholipid. Instead, Hanes et al particles are primarily composed of polymer (see columns 5 and 6). Papahadjopoulos et al does not make up for the deficiency in Hanes. Furthermore, there is no motivation for incorporating the calcium of Papahadjopoulos et al with the Hanes et al particles. Thus, there is no prima facie case of obviousness established against claim 57, as amended.

For at least these reasons, claim 57 is not properly rejectable under 35 USC §103(a) as being unpatentable over Hanes et al and Papahadjopoulos et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Papahadjopoulos et al could be applied, with a reasonable likelihood of success, to Hanes et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 57 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that invention set forth in claim 57 is particularly useful for delivering an active agent to the lungs in a reproducible manner. Thus, claim 57 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 57 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 59-79 which depend from claim 57 and are not rendered unpatentable by Hanes et al and Papahadjopoulos et al for at least the same reasons as claim 57.

Hanes et al and Papahadjopoulos et al also do not render independent claim 80,



for example, unpatentable. Claim 80 is to a composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, inter alia a structural matrix comprising phospholipid and calcium. Hanes et al does not teach an inhaleable powder comprising particulate microstructures comprising phospholipid and calcium (as acknowledged by the Examiner). Papahadjopoulos et al does not teach the addition of calcium in a manner where one of ordinary skill in the art would have found it obvious to arrive at the invention of claim 80, as discussed in the Applicant's previous response.

In addition, Hanes et al and Papahadjopoulos et al do not render claim 80 as amended, unpatentable. Claim 80 recites: "wherein the particulate microstructures comprise greater than about 50% phospholipid." Hanes et al does not teach particulate microstructures that comprise greater than about 50% phospholipid. Instead, Hanes et al particles are primarily composed of polymer (see columns 5 and 6). Papahadjopoulos et al does not make up for the deficiency in Hanes. Furthermore, there is no motivation for incorporating the calcium of Papahadjopoulos et al with the Hanes et al particles. Thus, there is no prima facie case of obviousness established against claim 80, as amended.

For at least these reasons, claim 80 is not properly rejectable under 35 USC §103(a) as being unpatentable over Hanes et al and Papahadjopoulos et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Papahadjopoulos et al could be applied, with a reasonable likelihood of success, to Hanes et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 80 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that invention set forth in claim 80 is particularly useful for delivering an active agent to the lungs in a reproducible manner. Thus, claim 80 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 80 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 82-102 which depend from claim 80 and are not rendered unpatentable by Hanes et al and Papahadjopoulos et al for at least the same reasons as claim 80.

The Examiner rejected claims 78 and 101 under 35 USC §103(a) as being unpatentable over Hanes et al in view of Papahadjopoulos et al, and further in view of Igarashi et al. The rejection is traversed.

Claims 78 and 101 depend from claims 57 and 80, respectively. Hanes et al and Papahadjopoulos et al do not render claims 57 and 80 unpatentable, as discussed above. Igarashi et al which is relied on by the Examiner to teach the use of antibiotics as an active agent does not make up for the deficiencies of Hanes et al and Papahadjopoulos et al with regard to claims 57 and 80. Thus, claims 78 and 101 are allowable for at least the reason that they depend from allowable claims.

### **Claim rejections under judicially created doctrine of Double Patenting**

The Examiner provisionally rejected claims 57, 59-80 and 82-102 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Applications 09/851,226; 09/568,818; 10/750,934; and 10/982,191.

Since the present case is otherwise in condition for allowance, Applicant requests allowance of the present case. The issue of double patenting can then be taken up in the pending cases or in the present case when the claims are otherwise indicated to be allowable.

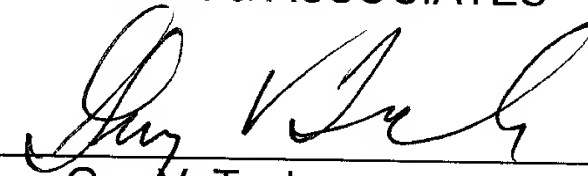
## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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